K050376

APR 7 2005

510(k) SUMMARY

This summary of safety and effectiveness is provided in accordance with 21 CFR 807.92.

Date of preparation: 14 February 2005

1. **Submitter**

Medical Technologies International, Inc. ("MTI")
74-980 Highway 111
Indian Wells, California 92210
FDA Owner/Operator Number: 9062380

Contact
Gary F. Thompson, Chairman & CEO
Medical Technologies International, Inc.
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2. **Device Identification**

Tradename: Prowin™
Common name: Medical image measurement software
Classification: 892.2050 – System, Image Processing, Radiological
FDA has classified these devices as Class II devices under FDA Product Code LLZ.

3. **Substantial Equivalence**

MTI believes that Prowin™'s measurement of IMT is substantially equivalent to other legally marketed products, specifically **Intelligence in Medical Technologies' M'Ath® Std (K040686), SonoMetric Health's SonoCalc™ (K030223)** and **ATL Ultrasound's (d.b.a. Philips Ultrasound) QLAB™** software package **(K021966)** when the latter is used for the automated measurement of carotid intima-media thickness.

4. **Device Description**

Prowin™ is a software program designed to measure carotid artery intima-media thickness from ultrasound images. Prowin™ operates on a stand-alone personal computer running a Microsoft Windows™ operating system.

Carotid artery images from any ultrasound machine are transferred to the

computer running Prowin™ by way of any media.

Following the transfer of images, Prowin™ uses proprietary, patent-pending techniques and algorithms to measure the intima-media thickness (IMT) of the near and/or far wall(s) of the carotid artery. The Prowin™ software package has the capability to generate a report indicating the IMT value.

5. Intended Use

The Prowin ™ software program is a Windows-based application used on a personal computer intended for viewing carotid ultrasound images and measuring arterial wall thickness. It is specifically indicated for the measurement of carotid artery far and near wall intima-media thickness (IMT) from images obtained from an ultrasound system. A physician may use this information in conjunction with other medical data in the assessment of a patient's cardiovascular risk.

6. Comparison with substantially equivalent devices

CHARACTERISTIC	PRINCIPLE DEVICE	PREDICATE DEVICE	PREDICATE DEVICE	PREDICATE DEVICE
	MEDICAL TECHNOLOGIES INTERNATIONAL, INC. (MTI)	INTELLIGENCE IN MEDICAL TECHNOLOGIES (IMT)	SONOMETRIC HEALTH, LLC	ADVANCED TECHNOLOGY LABORATORIES (ATL)
	PROWIN™	**M'ATH® STD (K040686)**	**SONOCALC™ (K030223)**	**QLAB™ (K021966)**
Intended Use	Automatic measurement of intima-media thickness of carotid arteries.	Automatic measurement of intima-media thickness of carotid arteries.	Automatic measurement of intima-media thickness of carotid arteries.	Automatic measurement of intima-media thickness of carotid and other arteries.
Image Source	Ultrasound images	Ultrasound images	Ultrasound images	Ultrasound images
Operating environment, system and hardware	Stand-alone application program for use on a personal computer operating with Microsoft Windows.	Stand-alone application program for use on a personal computer operating with Microsoft Windows.	Stand-alone application program for use on a personal computer operating with Microsoft Windows.	Stand-alone application program for use on a personal computer operating with Microsoft Windows.
Image Format	JPEG, Windows BMP, TIFF, & DICOM single file formats (DIC, DCM and ACR)	AVI, JPEG, GIF, TIFF, BMP, PCX, PCD, TGA, EPS, IMG	JPEG & Windows BMP	AVI, BMP, TIFF, & DICOM
Image Storage	Yes	Yes	Yes	Yes
Report Generation	Yes	Yes	Yes	Yes
Vascular Indices Related to Patient Database	Yes	Unknown	Yes (in labeling)	No

7. Performance Standards

There are no Section 514 performance standards for this class of device. The Prowin™ software package has been designed to comply with the following voluntary standards:

- ISO Joint Photographic Experts Group (JPEG) Image
- Microsoft Windows Bitmap (BMP) Image Encoding
- TIFF standard lossless format encoding
- DICOM single file images (DIC, DCM and ACR) as defined in the ACR-NEMA DICOM working group in 1993.
- Data Translation images converted to BMP

8. Performance Testing

As an indicator of measurement repeatability, data collected using Prowin™ software over the last 10 years showed the coefficient of variation to be <1%.

9. Conclusions

Based on available information, Prowin™ is substantially equivalent to predicate devices for viewing carotid ultrasound images and measuring arterial wall thickness. The Prowin™ software application has the same intended use and incorporates the same basic features and benefits of the described predicate devices cleared through premarket notification without raising any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Medical Technologies International, Inc.
% Mr. Marc Bozeman, Esq.
Partner
Hogan & Hartson, LLP
Biltmore Tower, 500 South Grand Avenue
Suite 1900
LOS ANGELES CA 90071

Re: K050376
Trade/Device Name: Prowin™ Medical Image Measurement Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 14, 2005
Received: February 14, 2005

Dear Mr. Bozeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050376

Indications for Use Statement

510(k) Number (if known): ~~Not assigned at this time.~~ K050376

Device Name: Prowin™ Medical Image Measurement Software

Indications for Use: The Prowin ™ software program is a Windows-based application used on a personal computer intended for viewing carotid ultrasound images and measuring arterial wall thickness. It is specifically indicated for the measurement of carotid artery far and near wall intima-media thickness (IMT) from images obtained from an ultrasound system. A physician may use this information in conjunction with other medical data in the assessment of a patient's cardiovascular risk.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ____ of ____

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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